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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,671	01/03/2005	Takashi Sera	1392/10/18/2 PCT/US	6533

25297 7590 10/05/2007  
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EXAMINER

DUNSTON, JENNIFER ANN

ART UNIT	PAPER NUMBER
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1636

MAIL DATE	DELIVERY MODE
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10/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/500,671

Applicant(s)

SERA, TAKASHI

Examiner

Jennifer Dunston

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-68 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

### **DETAILED ACTION**

Claims 1-68 are pending in the instant application.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-21, drawn to a chimeric protein comprising a first domain that is a nucleic acid binding domain and a second domain that is capable of associating with the nuclear periphery.

Group II, claim(s) 22-24 and 26-27, drawn to a nucleic acid molecule encoding a protein that comprises a first domain that is a nucleic acid binding domain and a second domain that is capable of associating with the nuclear periphery, an expression vector comprising said nucleic acid, and a host cell comprising said expression vector.

Group III, claim(s) 25, drawn to a method of producing a chimeric protein, comprising culturing a host cell under conditions to express the chimeric protein.

Group IV, claim(s) 28-39, drawn to a method of binding a target nucleic acid with a chimeric protein.

Group V, claim(s) 40-57, drawn to a molecular switch system comprising a first fusion protein comprising a first domain capable of binding a nucleotide sequence and a second domain capable of binding to a first binding moiety of a divalent ligand, and a second fusion protein comprising a first domain capable of associating with the nuclear periphery and a second domain capable of binding to the second binding moiety of the divalent ligand.

Group VI, claim(s) 58-62 and 64-65, drawn to a nucleic acid encoding a first protein and/or a second protein, wherein the first protein comprises a first domain capable of binding a nucleotide sequence and a second domain capable of binding to a first binding moiety of a divalent ligand, and the second protein comprises a first domain capable of associating with the nuclear periphery and a second domain capable of binding to the second binding moiety of the divalent ligand, an

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expression vector comprising said nucleic acid, and a host cell comprising said expression vector.

Group VII, claim(s) 63, drawn to a method of making a fusion protein comprising culturing cells comprising expression vectors encoding one or both of two fusion proteins.

Group VIII, claim(s) 66-68, drawn to a method of temporally or spatially repressing expression of a target gene, comprising contacting a cell or organism with a molecular switch system comprising a first fusion protein comprising a first domain capable of binding a nucleotide sequence and a second domain capable of binding to a first binding moiety of a divalent ligand, and a second fusion protein comprising a first domain capable of associating with the nuclear periphery and a second domain capable of binding to the second binding moiety of the divalent ligand.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-VIII do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The technical feature linking Groups I-IV appears to be that they all relate to a chimeric protein comprising a nucleic acid binding domain and a heterologous domain capable of associating with the nuclear periphery, such as a HP1 heterochromatin binding protein. However, Nielsen et al (The EMBO Journal, Vol. 18, No. 22, pages 6385-6395, 1999) teach a chimeric protein comprising a Gal4 DNA binding domain and a heterologous HP1 domain (e.g., page 6390, paragraph bridging columns). Therefore, the technical feature linking the inventions of Groups I-IV does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Furthermore, Groups V and VI do not share a significant common structure with Group I in that they are drawn to protein and nucleic acid molecules encoding proteins where the DNA binding domain and the heterologous domain capable of associating with the nuclear periphery are on separate molecules rather than the same molecule as required by Group I. Moreover, Groups VII and VIII are drawn to methods that do not make or use the chimeric protein of Group I and thus do not have a common technical feature with Group I.

Accordingly, Groups I-VIII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

This application contains claims directed to more than one species of the generic invention for Group I. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

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The species are composed of two subspecies as follows:

(A) type of nucleic acid binding domain (for example, zinc finger protein, leucine zipper protein, helix-turn-helix protein, helix-loop-helix protein, or a specific combination thereof, as recited in claim 2); and

(B) type of domain capable of associating with the nuclear periphery (for example, GCL protein (e.g., claim 13), HP1 (e.g., claim 16), polycomb-group protein (e.g., claim 16)).

Applicant is required, in reply to this action, to elect a single species (one combination of nucleic acid binding domain and domain capable of associating with the nuclear periphery, i.e., one chimeric protein) to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: claim 1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Nielsen et al (The EMBO Journal, Vol. 18, No. 22, pages 6385-6395, 1999) teach a chimeric protein comprising a Gal4 DNA binding domain and a heterologous HP1 domain (e.g., page 6390, paragraph bridging columns). Therefore, the feature linking the species is not a contribution over the prior art.

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This application contains claims directed to more than one species of the generic invention for Group IV. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are composed of two subspecies as follows:

(A) type of nucleic acid binding domain (for example, zinc finger protein, leucine zipper protein, helix-turn-helix protein, helix-loop-helix protein, or a specific combination thereof, as recited in claim 2);

(B) type of domain capable of associating with the nuclear periphery (for example, GCL protein (e.g., claim 53), HP1 (e.g., claim 56), polycomb-group proteins (e.g., claim 56)); and

(C) type of domain capable of binding to a divalent ligand (binding partner) (for example, single chain variable region of an antibody (e.g., claim 41, S-protein and S-tag (e.g., claim 43)).

Applicant is required, in reply to this action, to elect a single species (a first chimeric protein and a second chimeric protein made up of species subtypes A, B and C) to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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The following claim(s) are generic: 40.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each combination of protein domains is structurally and functionally different. Each type of domain does not share a significant structural element, and each combination of the distinct elements is also distinct.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

### ***Rejoinder Practice***

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected

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process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached at 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Dunston, Ph.D.  
Examiner  
Art Unit 1636

/JD/

CE AN, PH.D.  
PRIMARY EXAMINER

